

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher, et al.

Serial No. NA

Filed: Herewith

For: Deglycosylated Ricin Toxin A-chain
Vaccine

Art Unit: 1644

Examiner: NA

Atty. Docket: 12694/P66821US2
(RIID 99-12)

#7/a
12/18/01

Preliminary Amendment

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to initial examination, please amend the above-identified application as follows:

In the specification:

Please replace the first paragraph on page one of the specification with the following:

This application is a continuation of U.S. patent application Serial No. 09/523,271, filed on 10 March 2000, entitled Deglycosylated Ricin Toxin A-Chain Vaccine, naming Robert W. Wannemacher and John F. Hewetson as inventors, which claimed the benefit of priority from U.S. provisional patent application Serial No 60/124,283, filed on 12 March 1999.

In the claims:

Please cancel claims 1-16.

Please add the following claims:

17. (New) A method of inducing a mean ELISA antibody titer of about 1×10^2

against ricin toxin or more in a subject comprising administering to the subject an amount
of a deglycosylated ricin A-chain.

18. (New) The method of claim 1, wherein the deglycosylated ricin-A chain is
chemically deglycosylated.

19. (New) The method of claim 1, wherein the deglycosylated ricin A-chain is
incompletely deglycosylated.

20. (New) The method of claim 19, wherein mannose and fructose are absent
from the deglycosylated ricin A-chain.

21. (New) The method of claim 17, wherein the amount is an immunogenic
amount.

22. (New) The method of claim 21, wherein the immunogenic amount is about
0.1 μ g to about 10.0 μ g per about 20 g to about 25 g of the weight of the subject.

23. (New) The method of claim 17, wherein two doses an immunogenic amount
of a deglycosylated ricin A-chain are administered to the subject.

24. (New) The method of claim 17, further comprising administering an
adjuvant to the subject.

25. (New) A method for providing neutralizing antibodies against ricin toxin or
preventing ricin intoxication in a subject comprising administering at least two doses of
an immunogenic amount of a chemically deglycosylated ricin A-chain to the subject.

C1
Q2

26. (New) The method of claim 25, wherein the chemically deglycosylated ricin A-chain is incompletely deglycosylated.

27. (New) The method of claim 26, wherein mannose and fructose are absent from the chemically deglycosylated ricin A-chain.

28. (New) A vaccine against ricin intoxication comprising a chemically deglycosylated ricin A-chain in an immunogenic amount, wherein the immunogenic amount of the chemically deglycosylated ricin A-chain provides a mean ELISA antibody titer of about 1×10^2 or more in a subject.

29. (New) The vaccine of claim 28, wherein the chemically deglycosylated ricin A-chain is incompletely deglycosylated.

30. (New) The vaccine of claim 28, wherein mannose and fructose are absent from the chemically deglycosylated ricin A-chain.

31. (New) The vaccine of claim 28, wherein two doses of the immunogenic amount of the chemically deglycosylated ricin A-chain provides neutralizing antibodies in a subject.

32. (New) The vaccine of claim 28, wherein two doses of an immunogenic amount of the chemically deglycosylated ricin A-chain prevents ricin intoxication in a subject.

33. (New) A pharmaceutical composition comprising a chemically deglycosylated ricin A-chain in an effective immunogenic amount in a pharmaceutically acceptable carrier and/or adjuvant, wherein the immunogenic amount of the chemically deglycosylated ricin A-chain provides a mean ELISA antibody titer of about 1×10^2 or more in a subject.

Qnt
Qd

34. (New) The pharmaceutical composition of claim 33, wherein the chemically deglycosylated ricin A-chain is incompletely deglycosylated.

35. (New) The pharmaceutical composition of claim 33, wherein mannose and fructose are absent from the chemically deglycosylated ricin A-chain.

36. (New) An immunogenic composition comprising, in a physiologically acceptable vehicle, a chemically deglycosylated ricin A-chain, which provides a mean ELISA antibody titer of about 1×10^2 or more in a subject.

37. (New) The immunogenic composition of claim 36, further comprising a adjuvant to enhance the immune response.

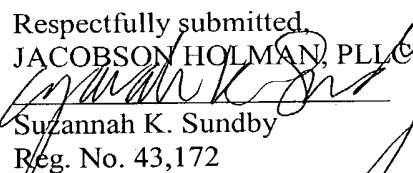
38. (New) The immunogenic composition of claim 36, wherein the chemically deglycosylated ricin A-chain is incompletely deglycosylated.

39. (New) The immunogenic composition of claim 36, wherein mannose and fructose are absent from the chemically deglycosylated ricin A-chain.

REMARKS

The foregoing Preliminary Amendment is requested in order to place the claims in conformity with United States patent practice. No statutory new matter has been added. Therefore, the Applicants respectfully request that the amendment be entered.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. **210380**, referencing Attorney Docket No. **12694/P66821US2 (RIID 99-12)**.

Respectfully submitted,
JACOBSON HOLMAN, PLLC

Suzannah K. Sundby
Reg. No. 43,172

Date: 24 September 2001
The Jenifer Building
400 Seventh Street, N.W.
Washington, DC 20004-2201
(202) 662-8497

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

This application is a continuation of U.S. patent application Serial No.
09/523,271, filed on 10 March 2000, entitled Deglycosylated Ricin Toxin A-Chain
Vaccine, naming Robert W. Wannemacher and John F. Hewetson as inventors, which
claimed the benefit of priority from U.S. provisional patent application Serial No
60/124,283, filed on 12 March 1999. [This application claims the benefit of priority from
U.S. Application serial no. 60/124,283 filed March 12, 1999.]

F0042500 EPO 200507